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UPPFINNINGENS BENÄMNING: NEW MICROEMULSIONS

The present invention relates to novel microemulsions. More particularly, the invention relates to novel microemulsions, which can be used for entrapping airborne particles and especially for the prevention of symptoms in mammals indirectly or directly caused by such particles.

Background of the Invention.

Epidemiology.

Airway diseases caused by exposure to airborne allergens are major health problems to affluent societies. For example, the prevalence of allergic rhinitis (seasonal, perennial, and occupational) is 20% or more, and increasing. Accordingly, the American Asthma and Allergy Foundation recently reported that about 17 million annual visits to office-based physicians were attributed to allergic rhinitis. Also, they reported that 35 million Americans were allergic to pollen allergens. Besides the morbidity and socioeconomic consequences that these allergies carry themselves, they have been identified as risk factors for the development of asthma. Indeed, one way of preventing the development of bronchial asthma may be to treat the allergic rhinitis condition.

Upper respiratory tract infections (caused by viruses and bacteria) are also major health problems. For example, the common cold is a very prevalent disease: The number of common cold episodes has been estimated to be 5 per year in the 0-4 year old age group, dropping to 3 episodes per year in the 5-19 year old group. These infections have, notably in the case of the common cold, been identified as a major cause of exacerbations of asthma and "chronic obstructive pulmonary disease".

"Non-allergic, non-infectious (vasomotor) rhinitis" is a less prevalent condition (compared with allergic rhinitis and upper respiratory tract infections). Nevertheless, it is a common differential diagnosis of patients having nasal symptoms.

Chemical and physical aspects on disease-producing airborne paticles.

Pollens and allergens themselves, as well as viruses, bacteria, and other exogenous factors, occur as airborne particles. Pollens typically have diameters between 15-60 µm. Virus particles, on the other hand, are typically 0.1-0.5 µm in diameter, while the size of bacteria and other prokaryotes ranges widely from 0.1 to about 5 µm. Cigarette smoke, printing ink, and occupational factors, which may produce "non-allergic, non-infectious (vasomotor) rhinitis", may also be viewed as particles with a wide size range. In order to produce disease-processes and symptoms associated with allergic rhinitis, upper respiratory tract infections, and "non-allergic, non-infectious (vasomotor) rhinitis" the disease-producing particles must come in contact with the mucosal surface.

Disease mechanisms and clinical presentations.

Mechanisms leading to allergic rhinitis comprise the contact of inhaled pollens/allergens with the nasal mucosal lining and the interaction with immunocompetent and inflammatory cells residing in the nasal mucosa. Specific antibodies (immunglobulins) are located at the surface of some of these cells. The allergen cross-bridges with receptors on the cell surface, which results in an activation of these cells and in the release of inflammatory mediators. These mediators, in turn, act on certain cells and structures in the mucosa (e.g., glands, blood vessels, nerve endings) to produce inflammation and the symptoms of aller-

gic rhinitis, i.e., nasal itching/sneezing, secretions, and blockage.

Upper respiratory tract infections are caused by viruses and bacteria interacting with the mucosa of the upper airways. The most common cause may be rhinoviruses, which bind to specific mucosal receptors, an inflammatory response being produced. This process, in turn, produces symptoms of common cold (sneezing, watery secretions, reduced nasal patency and catarrhal symptoms with accompanying fever and headache).

"Non-allergic, non-infectious (vasomotor) rhinitis" is sometimes caused by airborne particles other than allergens and infectious agents. The pathophysiological processes give rise to a symptomatology that is very similar to that of allergic rhinitis. However, it is less clearly understood.

Established treatments.

The best treatment for type-I allergic diseases, such as allergic rhinitis, would be to avoid the allergen. However, this strategy is more or less impossible, particularly for airborn allergens including those carried by pollens. In addition, this line of resoning applies for infectious agents and particles causing "non-allergic, non-infectious (vasomotor) rhinitis".

There is currently no established pharmacological treatment for upper respiratory tract infections, except for antibiotics and other chemotherapeutics targeting bacteria, antiviral compounds targeting viruses, specifically influenza virus, as well as topical and oral decongestants.

A pharmacological treatment for allergic rhinitis currently comprises topical, oral and systemical glucocorticosteroids, topical and oral antihistamines, topical chromoglycates, oral leukotriene-antagonists, topical and oral decongestants, topical and oral anticholinergics,

and immunotherapy, i.e., repeated exposure to relevant allergens in order to produce a state of increased tolerability. However, there is no single pharmaceutical preparation/treatment available, which treats or reduces all symptoms of allergic rhinitis. The most successful treatment may be topical corticosteroids, but their use is associated with a potential risk of local and systemic adverse effects. Antihistaminic preparations are commonly used, but their efficacy is limited. Local decongestents, though used, are not recommended by physicians skilled in the art.

Antibiotics may be used to treat upper respiratory tract infections caused by bacteria. However, no treatment is available for the common cold (caused by viral infections) except for oral and nasal decongestants (alpha-agonists). The neuraminidase inhibitor zanamivir has recently been introduced for the treatment of Influenza A and B, but its efficacy is limited.

Treatments for "non-allergic, non-infectious (vasomotor) rhinitis" include topical glucocorticosteroids, topical anticholinergics, and topical capsaicin. Common for these treatments, however, is their limited efficacy.

Potentially novel treatments.

The best treatment for type-I allergic diseases, such as allergic rhinitis, would be to avoid the allergen. However, this strategy is more or less impossible, particularly for airborn allergens including those carried by pollens. In addition, this line of resoning applies for infectious agents and particles causing "non-allergic, non-infectious (vasomotor) rhinitis".

An attempt to overcome nasal mucosal exposure of airborne particles, including pollens, is shown in US 6,109,262, a special adhesive nasal filter being used, which physically collects airborne particles. The method

and filter disclosed is said to have therapeutic, protective or profylactic use.

Inter. Arch. Allergy Immunol. 121:85, 2000, teaches the usefulness of regularly applying a mineral oil to the nasal mucosa of patients with seasonal allergic rhinitis in order to reduce allergic symptoms. It is suggested in this document that fatty acids might be helpful in the prevention of allergic rhinitis. Topical application of fats, such as certain triglycerides and oils to the nasal mucosa, has also been marketed for treating dryness of the nasal mucosa (Nozoil®, Pharmacure Health Care AB, Sweden).

In DE 20016125 a nasal ointment for prophylaxis of inhalation-allergic reactions, especially hay fever, is shown. The ointment comprises a mixture of saturated hydrocarbons and tannin(s), a mechanical barrier film being formed that prevents allergens from entering the nasal mucosa. Likewise, JP 07258070 depicts a nasal rinsing agent for treating allergic rhinitis. The nose cleaning agent, which consists of an oil/water type of emulsion of pH 3.5-5.5, forms an oil film after spraying into a nasal cavity. As in DE 20016125, the oil is spread on the nasal mucosa and a non-homogenous film is formed.

The attachment of most rhinovirus subtypes to cells depends on a cellular receptor, the intercellular adhesion molecule 1 (ICAM-1). JAMA 1999,May 19;281(19):1797-804, teaches that recombinant soluble ICAM-1, inhaled as a solution or as a powder, reduces the severity of experimental rhinovirus common colds.

Accordingly, there is an obvious need for new and more efficacious treatments also in this topical area. Furthermore, like for allergic rhinits, there is a need for a way of preventing or reducing, in a preventive way, the above-mentioned symptoms associated with upper respiratory tract infections, such as common colds.

The Invention.

The objective of the invention is to provide a microemulsion for capturing airborne particles, whereby the above-mentioned problems are eliminated.

Another objective of the invention is to provide a microemulsion that is able to capture airborne particles and retard or inhibit their interactions with exterior mucosal membranes.

Still another objective is to provide a microemulsion that follows the mucus when swallowed or sneezed out.

A further objective of the invention is to provide a microemulsion that can wet pollen or virus and thus encapsulate them.

Yet a further objective is to provide a microemulsion that is sprayable.

Still yet a further objective is to provide a microemulsion for capturing airborne particles, which also can be used in filter devices.

These objectives are accomplished by a microemulsion comprising a surfactant, at least one polar solvent, a non-polar lipid, as well as a polar lipid.

We have surprisingly found that airborne particles, exemplified by virus, bacteria, pollen, allergens, dust, mould, fungus spores, animal dander, and other solid aerosol particles, can be trapped by the inventive microemulsion. No similar microemulsion has hitherto been disclosed.

The invention utilizes the inherent properties of an airborne particle, i.e. the particle can have a hydrophobic core and is at the same time electrostatically charged. Thereby the particle is conferred hydrophilic properties. However, the charge will immediately be lost when entering the nose and contacting a mucous membrane, which results in that the hydrophobic properties will dominate. Thus, when airborne, such particles (pollens etc.) have a hydrophilic

surface which must be substantially captured within a hydrophilic environment. Pure oils will not work, since they can not wet pollens or viruses and thus not encapsulate them.

Microemulsions typically look like clear solutions, but are thermodynamically stable dispersions of one liquid phase into another. The oil and water domains in the microemulsion exhibit a disordered and intricate microstructure. The extremely low interfacial tension of the oil/water interphase, the small droplet diameters of approximately 100 nm or less as well as water domains of a suitable size, are advantageous properties for capturing airborne particles.

Accordingly, airborne particles can be trapped by the specific self-assembled hydrophilic/hydrophobic structure provided by means of the invention. The inventive microemulsion is able to provide an environment, which substantially encloses (surrounds) the particles.

In addition, the inventive microemulsion does not contain any active agent, such as a drug or the like. This means that no side-effects are obtained, which originate from such agents.

Furthermore, a sprayable microemulsion can be provided, which contains large amounts of a polar solvent in order to reduce the viscosity. In addition, the inventive microemulsions are able to top spread homogenously on the mucosa and do not only function as a protective barrier but also as a capturing agent for airborne particles, which follows the mucus when swallowed or sneezed out.

The microemulsion according to the invention is effective for the protection of mucosal membranes that line all body cavities which are open to the exterior. Thus, peripheral membrane linings of the nose, the eyes, the ears, the pharynx, and the larynx. can be protected.

However, it is preferred to be used for capturing particles in the nasal cavity, the pharynx, and the larynx.

A microemulsion can be defined as a thermodynamically stable, transparent dispersion of two immiscible liquids, stabilized by an interfacial film of surfactants. In this connection a microemulsion is a clear thermodynamically stable dispersion of two immiscible liquids containing appropriate amounts of surfactants and co-surfactants.

The meaning of surfactant as used in the description and in the claims follows the current usage well known to those skilled in the art. A good surfactant should have a low solubility in both the bulk and dispersed phases of the microemulsion.

The surfactant is usually an organic polymer with a long chain hydrophobic tail and a small hydrophilic head group, and it can be anionic, nonionic, cationic or ampheoteric. Nonionic surfactants are preferred since they are less harmful to humans than ionic surfactants.

Suitable nonionic surfactants are polyoxyethylenated alkylphenols (mostly p-octyl-, p-nonyl-, p-dodecyl-, dinonylphenols), polyoxyethylenated straight chain alcohols, polyoxyethylenated polyoxypropylene glycols, polyoxyethylenated mercaptans, long chain carboxylic acid esters (glyceryl and polyglyceryl esters of natural fatty acids, propylene glycol, sorbitol, and polyoxyethylenated sorbitol esters, polyoxyethylene glycol esters) and alkanolamines (diethanolamine-, isopropanolamine-fatty acid condensates). The edible surfactants are mainly the esters based on glycerol, sorbitol, and propylene glycol.

Preferably, the surfactant is an amphiphilic compound such as a polysorbate, a poloxamer, or a fatty acid polyoxyethylene. It is most preferred that the amphiphilic compound is polysorbate 80.

Suitable ionic surfactants are succinic, citric, and diacetyl tartaric acid esters. Lecithin is the preferred surfactant containing a positive charge.

The required amount of surfactant is dependent on the other components used in the inventive microemulsion. However, the surfactant concentration should always exceed its critical micellar concentration (CMC).

The hydrophilic/hydrophobic balance, i.e. the molar ratio of hydrophilic to hydrophobic moieties, has a temperature maximum in the mutual solubility of the surfactant in water and oil. This maximum is adapted to encompass a temperature interval, within which the inventive microemulsion is intended to be used, for example around room and body temperatures. Preferably, the hydrophilic-hydrophobic balance of the surfactant, should not exceed 7. Thus, the surfactant comprises 0.1 to 20 %(wt/wt), preferably 1 to 10 % (wt/wt) of the microemulsion.

The surface tension between the two liquid layers of the microemulsion can be further lowered to approach zero by the addition of at least one polar solvent. Thus, the polar solvent may act as a cosurfactant in the inventive microemulsion and is preferably a small molecule that improves the stability of the microemulsion system. Increased amounts of polar solvent also reduces the viscosity, a better micro-viscosity being obtained in the microemulsion droplets.

Typical such polar solvents are short chain alcohols, ethanol to butanol, glycols, such as propylene glycol, or medium chain alcohols, amines, or acids. Preferred polar solvents are propylene glycols and/or polyethylene glycols and/or a saline solution.

Water and buffered aqueous media can also be used for solubilizing one phase into the other in the microemulsion system, which contain a variety of salts and buffers. Preferably, the salts are alkali and alkaline

earth halides, e.g. sodium chloride, potassium chloride, or sodium sulphate. Various buffers may be used, such as citrate, phosphate, HEPES, Tris, or the like to the extent that such buffers are physiologically acceptable for its purpose.

The polar solvent or solvents used in the inventive microemulsion should comprise 5 to 95 % (wt/wt), preferably 10 to 55 % (wt/wt) of the same. It is also preferred that the at least one polar solvent has a pH exceeding pH 5.5.

The polar lipid in the microemulsion can be an alcohol, an amine, cholesterol, a fat soluble vitamin, a glyceride, a phospholipide, a glycolipide, or a sphingolipide, or a mixture thereof. Preferably, the glyceride is a mono-acyl glyceride, for example glyceryl monooleate, glyceryl monolinoleate or glyceryl monolinenoleate.

The polar lipid may comprise 1 to 99 % (wt/wt), preferably 10 to 75% (wt/wt), most preferred 20 to 50 % (wt/wt) of the inventive microemulsion.

It is an important aspect of the invention that the microemulsion, which consists of a non-polar lipid, at least one polar solvent, a surfactant, and a polar lipid as sole ingredients, provides an environment that substantially encloses airborne particles.

The inventive microemulsion should also comprise one or more non-polar lipids, such as di-acyl glycerides, tri-acyl glycerides, mineral oils, paraffin oils and esters, as well as ethers or waxes of fatty acids having a total number of carbon atoms more than 22. Preferably, the non-polar lipid is a tri-acyl glyceride.

Excellent microemulsions are formed well by using non-polar oils, such as the normal alkanes, as the non-polar lipid. Triglycerides are preferred because they are edible.

Acceptable animal oils are cod liver oil, lanolin oil, mink oil, orange roughy oil, and shark liver oil.

Acceptable vegetable oils include almond, apricot kernel, avocado, castor, coconut, corn, evening primrose, jojoba, olive, safflower, sesame, soybean, and wheat germ oils. Some silicone oils are acceptable, such as certain linear polysiloxanes and cyclic dimethyl polysiloxanes such as cyclomethicone. It is preferred that the vegetable oil is sesame oil.

The non-polar lipid should comprise 1 to 99 % (wt/wt), preferably 5 to 75% (wt/wt), most preferred 5 to 35 % (wt/wt) of the microemulsion.

The microemulsion according to the invention can have a large number of applications where airborne particles have to be entrapped in the homogenous film formed. These include different kind of filter devices, which can be used for e.g. air cleaning and/or decontamination. However, the inventive emulsion is especially adapted for human use, i.e. to be applied to peripheral membrane linings of the nose, the eyes, the ears, the pharynx, and the larynx. for entrapping airborne particles.

The microemulsion can be applied locally. Local applications include for example spray and drops, pipettes made up in single doses, a powder obtained by lyophilization of the emulsion, a tamponage, or a painting. A nasal pool device can be used to apply controlled amounts of the emulsion on a human nasal airway mucosa. Preferably, a mouth or nasal spray device is used, which contains the inventive microemulsion.

Examples.

The invention will now be further described and illustrated by reference to the following examples. It should be noted, however, that these examples should not be construed as limiting the invention in any way.

Example 1. Preparation of an exemplary composition.

Twenty ml of a microemulsion was prepared, which had the following composition (w/w %):

Component	Amount (w/w %)
Glycerol monooleate	34
Propylene glycol	23
Polyethylene glycol 400	18
Sesame oil	11
Saline solution	10
Polysorbate 80	4

Example 2. Adverse effects.

The microemulsion according to Example 1 was filled on flasks equipped with a spray mechanism an administered to human volunteers. No signs or complaints of adverse effects were made.

Example 3. Prevention of pollen allergy.

In order to test the feasibility of a nasal provocation the microemulsion according to Example 1 was administered to the nasal cavity of 9 subjects by means of a nasal pool device (Greiff L et al. Clin Exp Allergy. 1990 May; 20(3):253-9). Also the placebo (saline solution) was administered with this device.

Rinsing was performed by loading and administrating 14 ml of saline solution with this nasal pool device.

Nasal provocations were performed at two occasions with at least one week in between. The study was of a single blind placebo controlled fashion. At one visit the microemulsion of Example 1 was given and at the other occasion the placebo (isotonic saline). Both treatments (microemulsion and placebo) were given in the nasal pool device (14 ml) in the right nasal cavity.

Before the challenge nasal symptoms were rated, followed by two nasal washings (each, one minute) using the pool device. These washings with 14 ml of saline were undertaken in order to reduce cell free mediators that have been accumulated on the nasal mucosal surface. Thereafter a 5 min saline washing was performed in order to establish a baseline.

The microemulsion and placebo (saline) were delivered by means of the pool device in a randomized order. The treatments (placebo and saline) were being kept in contact with the nasal mucosal surface for 2.5 minutes.

Then the treatment was released and the subjects assessed symptoms once more. Five min after the treatment delivery a nasal allergen challenge with a moderate dose of allergen was given in the same nasal cavity in the same way as the previous washings and treatments had been delivered (right nasal cavity). The subjects performed 10 min after allergen challenge a third symptom assessment and a second 5 min washing was performed as well. Both 5 min washings were collected and immediately cold centrifuged at 2000 rpm and frozen (-18°C) for later analysis.

Nasal symptoms were scored, as previously described, prior to challenge (baseline), immediately before challenge (prior) and 10 min after allergen challenge. Nasal symptoms, runny nose, and blockage were scored 0 = no symptoms, 1 = mild symptoms, 2 = moderate symptoms, 3 = severe symptoms. In addition, the number of sneezes were counted.

Sneezing.

The number of sneezes were determined at baseline, prior to and 10 min after allergen challenge in 9 subjects with pollen allergy after pretreatment with the microemulsion and placebo.

Allergen induces sneezes in the allergic subjects both after microemulsion and placebo treatment with no significant differences between the treatments.

Rhinitis.

A subjective assessment of nasal secretion was also performed at baseline, prior to and 10 min after allergen challenge, in 9 subjects with pollen allergy after pretreatment with the microemulsion and placebo.

Allergen induces nasal secretion in the allergic subjects both after treatment with microemulsion and placebo with no significant differences between the treatments.

Nasal congestion.

Likewise, a subjective assessment of nasal congestion was performed at baseline, prior to and 10 min after allergen challenge, in 9 subjects with pollen allergy after pretreatment with the microemulsion and placebo.

Allergen challenge increases nasal congestion in the allergic subjects both after treatment with microemulsion and placebo. However, the microemulsion significantly reduces nasal congestion as compared to placebo (*= $p<0.05$).

Total nasal symptom score.

FIG 1 shows the assessment of total nasal symptom score with reference to sneezing, secretion, and nasal congestion.

Allergen challenge increases the total nasal symptom score in the allergic subjects both after treatment with microemulsion and placebo. However, the microemulsion significantly reduces total symptoms as compared to placebo (*= $p<0.011$).

Example 4. Nasal mucosal inflammation.

α2-Macroglobulin was measured in nasal washings as an index of nasal mucosal inflammation. Samples were collected prior to and 10 min after allergen challenge in 9 subjects

with pollen allergy after treatment with the microemulsion according to Example 1 and placebo.

As shown in FIG 2, the allergen challenge induces a significant increase in nasal mucosal output of α2-macroglobulin after placebo treatment (*=$p<0.01$), but not after treatment with the microemulsion. Furthermore, a significant difference in the levels of α2-macroglobulin is seen between microemulsion and placebo 10 min after allergen challenge (*=$p<0.05$).

CLAIMS

1. A microemulsion comprising a non-polar lipid, at least one polar solvent, and a surfactant, c h a r a c - t e r i z e d in that it further comprises a polar lipid.

2. The microemulsion as in claim 1, c h a r a c - t e r i z e d in that said polar lipid is an alcohol, an amine, cholesterol, a fat soluble vitamin, a glyceride, a phospholipide, a glycolipide, or a sphingolipide, or a mixture thereof.

3. The microemulsion as in claim 1, c h a r a c - t e r i z e d in that said non-polar lipid is a di-acyl glyceride, a tri-acyl glyceride, a vegetable oil, a mineral oil, a paraffin oil, a paraffin ester, an ether or a wax of fatty acids having a total number of carbon atoms of more than 22.

4. The microemulsion as in claim 1, c h a r a c - t e r i z e d in that said at least one polar solvent is water, a buffer, a glycol, an alcohol, or a mixture thereof.

5. The microemulsion as in claim 1, c h a r a c - t e r i z e d in that said surfactant has a hydrophilic-hydrophobic balance exceeding 7.

6 The microemulsion as in claim 1, c h a r a c - t e r i z e d in that said surfactant is a polysorbate, a poloxamer, or a fatty acid polyoxyethylene.

7. A microemulsion for entrapping airborne particles, c h a r a c t e r i z e d in that it consists of a non-polar lipid, at least one polar solvent, a surfactant, and a polar lipid as sole ingredients, an environment being provided that substantially encloses said particles.

8. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said polar lipid comprises 20 to 50 % (wt/wt) of said microemulsion.

9. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said polar lipid is an alcohol, an amine, cholesterol, a fat soluble vitamin, a glyceride, a phospholipide, a glycolipide, or a sphingolipide, or a mixture thereof.

10. The microemulsion as in claim 9, c h a r a c - t e r i z e d in that said glyceride is a mono-acyl glyceride.

11. The microemulsion as in claim 10, c h a r a c - t e r i z e d in that said mono-acyl glyceride is glyceryl monooleate, glyceryl monolinoleate or glyceryl monolinenoleate.

12. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said non-polar lipid comprises 5 to 35 % (wt/wt) of said microemulsion.

13. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said non-polar lipid is a di-acyl glyceride, a tri-acyl glyceride, a vegetable oil, a mineral oil, a paraffin oil, a paraffin ester, an ether or a wax of fatty acids having a total number of carbon atoms of more than 22.

14. The microemulsion as in claim 13, c h a r a c - t e r i z e d in that said vegetable oil is sesame oil.

15. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said surfactant has a hydrophilic-hydrophobic balance exceeding 7.

16. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said surfactant is a polysorbate, a poloxamer, or a fatty acid polyoxyethylene.

17. The microemulsion as in claim 16, c h a r a c - t e r i z e d in that said polysorbate is polysorbate 80.

18. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said at least one polar solvent comprises 5 to 95 % (wt/wt), preferably 10 to 55 % (wt/wt) of said microemulsion.

19. The microemulsion as in claim 7 c h a r a c - t e r i z e d in that said at least one polar solvent has a pH exceeding pH 5.5.

20. The microemulsion as in claim 7, c h a r a c - t e r i z e d in that said at least one polar solvent is water, a buffer, a glycol, an alcohol, or a mixture thereof.

21. The microemulsion as in claim 20, c h a r a c - t e r i z e d in that said at least one polar solvent is propylene glycol and/or polyethylene glycol and/or saline solution.

22. A mouth or nasal spray device containing the microemulsion as claimed in claim 7.

23. A filter device comprising the microemulsion as claimed in claim 7.

ABSTRACT

The invention relates to novel microemulsions comprising a non-polar lipid, at least one polar solvent, a surfactant, and a polar lipid. A microemulsion of these ingredients solely provides an environment that substantially encloses airborne particles, and it can be used for entrapping such particles. The inventive microemulsions are especially adapted for the prevention of symptoms in mammals, which are indirectly or directly caused by airborne particles.

FIG 1

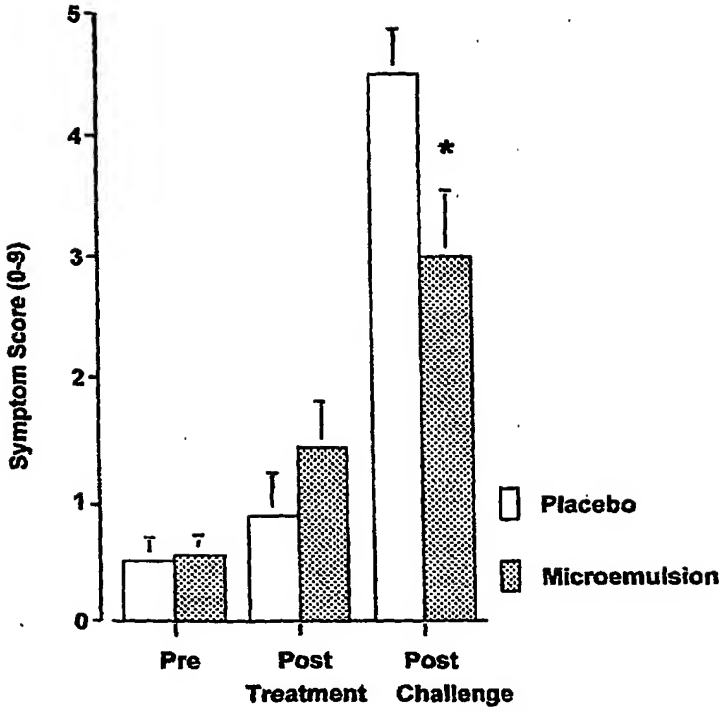
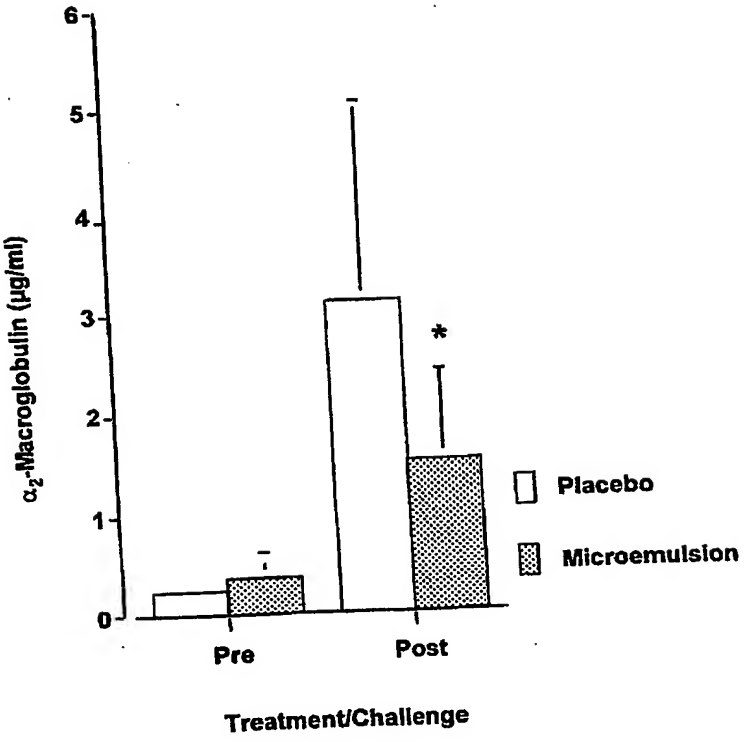


FIG 2


6
5
4
3
2
1
0
α_2-Macroglobulin (µg/ml)
*
Placebo
Microemulsion
Pre
Post
Treatment/Challenge